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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 33

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Appellant(s): MICHELSON, GARY K.

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For Appellant

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EXAMINER'S ANSWER

This is in response to the appeal brief granted 2 December 2002.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

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(3) Status of Claims

The statement of the status of the claims contained in the brief is correct. However, the amendment filed along with the brief has been entered and overcame the 35 USC 112 second paragraph rejection of claim 19 and therefore has been withdrawn.

(4) Status of Amendments After Final

The amendment after final rejection filed on 23 July 2002 has been entered.

(5) Summary of Invention

The summary of invention contained in the brief is not accurate and misleading because in lines 12-14 on page 3 of the brief, appellant states "At least a portion of the flexible projections 116 extending a distance from the central axis of shaft 112 greater than the width of flexible member 118 (Fig. 5)." However there is no support in the specification for such a limitation. Appellant points to figure 5 for support however, no such detail can be gleaned from the drawing. In fact if one were to draw a straight line from the apex of the flexible projections 116 from figure 6 back to the flexible member 118, it would appear that they extend the same distance. There is nothing in the written description to cover such a limitation.

On page 4, lines 10-12, appellant states “in which no more than two of the apexes of flexible projections 116 are in one plane perpendicular to the longitudinal axis of shaft 112 at any point along shaft 112 (Figs. 5 and 6).” However, there is no support in the written specification or drawings for this limitation. Appellant points to figures 5 and 6 for support however, no such details can be gleaned from these drawings. Figure 5 would appear to show the flexible projections are formed in a plurality of parallel rows. The four end flexible projections would appear to lie in the same perpendicular plane not more than just two.

On page 4, lines 15-17, appellant states that the flexible member 118 has a greater surface area to mass ratio than the hollow shaft 112 for permitting a higher absorption rate of the bioabsorbable material. Appellant relies on figure 5 for support for this claim however, no such detail can be gleaned from the drawing. The portion of the specification appellant points to merely describes the bioabsorbable composition of the overall device. There is no support for the specific ratio claimed.

Since appellant is relying patentability on these limitations it is not clear why there is no mention of these details in the written description. If these features are so important to the invention then why doesn't the specification even mention them?

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that all of the claims do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

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(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5261914	Warren	11-1993
4976715	Bays et al.	12/1990
4548202	Duncan	10-1985

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

Claims 19-24 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 19, the language “the sum of the height of one of said flexible projections and the radius of said shaft being greater than the radius of said flexible member” has no support in the written specification and cannot be fairly interpreted from the drawings. Basically, the language says that the flexible projections 116 extend away from the central axis further than the flexible member 118.

As far as the drawings are concerned, drawing a straight line from the tips of the projections 116 to the tip of the flexible member 118 from any of figures 6-8 yields that they are about the same height. It cannot be ascertained from any drawing that the projections 116 extend out a further distance than the flexible member 118. Details such as these cannot be ascertained

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from the drawings with any specificity. Moreover the specification does not even mention this critical feature that leads one to wonder why is the patentability hinging on this feature when it isn't described in the written description?

Appellant points to a section of the specification for support for this limitation however, appellant is mixing the numbers from a larger embodiment with the numbers of a smaller embodiment to achieve support. This is misleading and will be described in detail later.

The rejection of claim 19 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of the 23 July 2002 amendment. With the amendment of 23 July 2002 to claim 19, the language at the bottom of the claim has been clarified as to its meaning thereby overcoming the 112 2nd paragraph rejections.

Claim 24 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 24 remains rejected because it is unclear what appellant is attempting to claim. Claim 24 recites that "no more than two said apexes of said flexible projections are in one plane perpendicular to the longitudinal axis of said shaft at any point along said shaft". It would appear in all of the drawings the projections all extend in the same perpendicular plane.

Therefore there are always four projections in a plane perpendicular to the longitudinal axis.

There is also no support in the specification for this critical feature. It is not clear how appellant can claim that no more than two projections lie in a perpendicular plane when it appears all four projections lie in the same perpendicular plane.

Claim Rejections - 35 USC § 103

Claims 19, 22 and 26-28 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Warren. Warren discloses the same surgical rivet arrangement as that claimed by appellant. He discloses that the rivet has a hollow shaft and a number of projections extending from said shaft and the flexible member at the other end. He also discloses that the rivet is made of biodegradable material, copolymers of glycolide, the same material used by appellant. Warren also teaches that the material is intended to be resilient such that the projections deform upon insertion. Due to the fact that the rivet of Warren is made of the same material as the instant invention and that this material has to be resilient in order to perform, it would appear that rivet of Warren would comprehend the claimed resilient characteristic at least to some extent. It is not clear exactly how the claimed rivet is different from Warren's rivet however, it would have been obvious to modify the rivet of Warren as desired so that its head was flexible enough to conform to the angle of the tissue. This modification would have been obvious for one of ordinary skill to have the rivet in flush contact with the tissue so that a smooth transfer surface would be formed, thereby insuring that nothing would be caught on the extending rivet head and damaged. Making the head of screws, rivets and the like flush has always been a problem solved through routine experimentation.

Claims 20 and 21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Warren in view of Bays et al. Warren discloses the rivet as discussed above. He does not disclose the driver as claimed.

Bays teaches the driver as discussed in the previous office action. It would have been obvious to one of ordinary skill in the art to modify the rivet of Warren with the driver as taught

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by Bays to complete the operation of installing the rivet in use. This would have been obvious for Bays teaches that his driving means allows the user to apply the force necessary to correctly place the rivet within the tissue. Appellant is to note that the lengths of his driver's elements are well within the realm of the artisan of ordinary skill and is not inventive to discover the optimum or workable ranges by routine experimentation.

Claims 23 and 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Warren in view of Duncan. Warren may not teach the staggered projections as claimed however Duncan teaches rivets that have radially staggered projections. It would have been obvious to one of ordinary skill in the art to modify the rivet of Warren to stagger the projections as taught by Duncan so the rivet will be better secured within the body.

(11) *Response to Argument*

Regarding the §112 first paragraph rejection, appellant relies on page 8 lines 3-12 for support by calculating the radius of the flexible projection and comparing it to the radius of the flexible member however, what appellant is doing is comparing two different embodiments. Lines 3-10 describe an embodiment that has a 2.0 mm diameter shaft and lines 11-16 are describe an embodiment that has a 1.25 mm diameter shaft. Appellant takes the radius of the shaft of the smaller embodiment and subtracts it from the radius of the flexible member of the larger embodiment. This gives a misleading dimension of the height of the flexible member. At the beginning of the third line from the bottom of page 7 of the brief appellant states that the diameter of the shaft is taken from page 8, line 12 of the specification and at the beginning of the second line from the bottom of page 7 of the brief appellant states that the diameter of the flexible member is taken from page 8, line 6 of the specification. In the specification page 8 one

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can clearly see that line 12 is under line 11 that states "In the alternative embodiment of the present invention...." which is a smaller embodiment from the lines above line 11 which is where appellant got the dimension for the flexible member in line 6 and is the larger sized embodiment. Appellant takes the radius of the smaller rivet being 0.625 mm, half of the smaller diameter 1.25 mm, and subtracts that from the outer radius of the flexible member 118 of the larger rivet being 1.25 mm, half of the larger diameter dimension 2.5 mm. This yields a number that is not a true dimension in any embodiment. Moreover, appellant takes this false dimension 0.625 mm, which is supposed to be the height of the flexible member above the outside surface of the shaft, and compares it to the raw radius of the projections which appellant states has to be greater than 1 mm because the overall diameter of the rivet is 2 mm. The second number includes the diameter of the shaft whereas the first number subtracts the diameter of the shaft. None of these arguments make any sense.

On page 8 lines 8-14 of appellant's brief, appellant quotes the examiner to say that the projections extend a greater distance than the flexible member however, this quote is taken out of context. This quote was an attempt to clarify the §112 second paragraph problem with the language describing the height of the projections being greater than the height of the flexible member. The original language in the claim was comparing the radius of the projections to the diameter of the head which was confusing. The amendment filed with the brief has clarified this problem and is now moot.

Regarding the rejection of claim 24, appellant states that claim 24 depends on claim 23 which states that the flexible projections are staggered and points to figure 6. Yes this is true they are staggered radially about the outer surface of the shaft. They are staggered at about 90°

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intervals. This has nothing to do with whether or not no more than two projections lie in a plane perpendicular to the longitudinal axis. The written description doesn't support such a claim and the drawings are not drawn to scale so the drawings don't support such a claim.

Regarding the §103 rejection of claims 19, 22 and 26-28, Warren may not teach that the projections extend a greater distance than the flexible member however, appellant's invention doesn't either and therefore Warren doesn't have to show it. Appellant can't support such a limitation and therefore Warren doesn't either.

Warren may not describe the flexibility of the head however, since appellant's invention and Warren's invention is made of the same material and that Warren states that the fastener is formed out of a resilient material it would appear that Warren's fastener would comprehend the claimed invention. It is not clear how it would differ since they are made of the same material. The projections or ribs 135 have to deform upon engagement with the tissue in the same manner as appellants. Warren teaches that another part of the fastener is flexible, appellant is merely describing how the head is also flexible. Since they are made of the same material how is the head any different from the instant invention?

However, to any extent the head of Warren is some how different from the instant invention, it would have been obvious to make it more flexible so that the head conforms to the angle of the surface of the tissue to prevent any portion of the head from extending outwardly forming a sharp edge that would be damaging to the patient. Such consideration is not new and is well within the realm of the artisan of ordinary skill.

Appellant argues that Warren uses a fillet 161 at the junction of shank portion 115 and lower surface 160 of head 110 however, there is no claim limitations precluding the presents of a

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fillet. While fillets are commonly used to join the head to the shank, there is nothing in the specification that says the instant invention can't have a fillet.

Appellant argues that Warren states that the fastener has to be struck repeatedly in order to move the fastener into place however, so does appellant's. That is the purpose of appellant's driver 130. The handle 131 has a surface that mates with the head 118 to drive the fastener into the tissue. Again they operate in the same manner.

Appellant argues that the examiner has not provided any grounds of rejection for claim 22 however claim 22 falls with claim 19 because Warren clearly anticipates the at least five flexible projections in figure 9. No argument was given because it was understood that appellant could read the reference.

Regarding claim 26, the limitation that the flexible member "has a greater surface area to mass ratio than said hollow shaft for permitting a higher absorption rate" is not supported by appellant's disclosure and therefore Warren doesn't have to show it. Appellant argues how Warren's fastener doesn't teach the recited limitation however appellant hasn't provided any support of how the specification of the instant invention supports such a limitation. The same would apply to claim 27 and the limitation "whereby said flexible member at the rear end is absorbed prior to said hollow shaft so that the flexible member at the rear end does not separate from said hollow shaft."

Regarding claims 20 and 21 and the application of Bays et al., it is not clear how appellant can disregard the teaching of Bays. Warren teaches that the fastener has to be driven in place but fails to show how the fastener is driven in place. Bays provides the device in which to drive the fastener in place. The driver has the shaft that would fit within the hollow shaft of the

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fastener and be driven in place just the same. While Bays includes the J-configuration to help hold the fastener to the driver, there are no claim limitations that somehow preclude this additional feature. The J-configuration could just as easily be applied to the Warren fastener.

Regarding claim 21 and the limitation "the length of said rod from the handle to said tapered tip is the length of said rivet", Bays would appear to comprehend this language as shown in figure 2. The function of forming a smooth transition between the driving means and the conical penetration head is still achieved by Bays. Any difference is a matter of degree. The intended purpose of the pointed end of the driver is to aid the penetration of the driver and fastener through body tissue. The purpose of the pointed end is to provide a smooth transition for the fastener. If there is any difference between the length of the shaft and the length of the fastener is a matter of degree and an obvious provision to one of ordinary skill in the art.

Regarding claim 23, it is not clear how appellant can disregard the teaching of Duncan. Duncan teaches the continuous barbs in figures 1-7 and shows the discontinuous barbs in figures 8+. Warren teaches continuous barbs just as Duncan does in figures 1-7 but as taught by Duncan in figures 8+ discontinuous barbs are an obvious equivalent alternative. Appellant argues that Duncan's barbs are not radially staggered. That they are uniformly aligned along the radius of the legs of the fastener. That may be true too. The barbs of Duncan are radially staggered 90° just as appellant's barbs are radially staggered 90° and are uniformly aligned just as appellant's. It is not clear how they are different.

Regarding claim 24, the limitation that no more than two projections are in one plane perpendicular to the longitudinal axis of the shaft is not supported by the specification of the

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instant invention and therefore the prior art doesn't have to show it. Appellant can't make the claim and therefore the prior art doesn't have to make it either.

Conclusion

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



Danton DeMille

Primary Examiner

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February 21, 2003

Conferees

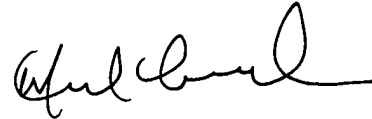
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